REMARKS

The Office Action mailed February 25, 2004 has been received and carefully considered. Upon entry of the preceding amendments, claims 1-7, 9-20, 23-24, 26, and 28-61 will be pending. In the Office Action, the Examiner acknowledges Applicant's Request for Continued Examination (RCE) and has withdrawn the finality of the previous Office Action pursuant to 37 C.F.R. § 1.114.

Claims 1-7, 18, 20, 26, 28, 41-46 and 48 stand rejected under 35 U.S.C. § 102(b) as assertedly anticipated by RU 2034465 to Pavlyk ("Pavlyk"). Claims 1, 3, 5, 6, 18, 20, 26, 41, 46, and 47 stand rejected under 35 U.S.C. § 102(b) as assertedly anticipated by WO 96/04943.

Claims 1-7, 9-15, 18-20, 23, 24, 26, 28-36, and 41-49 stand rejected as obvious over U.S. Pat. No. 6,335,028 to Vogel et al. ("Vogel"). Claims 1-7, 9-15, 18-20, 23, 24, 26, and 28-49 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of copending applications 09/938,668 and 09/938,669. Claims 1-7, 9-15, 17-20, 23, 24, 26, and 28-49 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of copending application 09/938,670.

Claim 16 has been objected to, but has been identified as containing patentable subject matter.. Additionally, claims 17 and 37-40 have only been rejected under the double patenting rejection and thus are also directed to subject matter patentable once the double patenting rejection is overcome, e.g. by filing a terminal disclaimer. Applicant expresses his appreciation for the indication of allowable subject matter. Reconsideration in light of the preceding amendments and the remarks which follow is respectfully requested.

I. IDS filed October 9, 2003.

In the Office Action, the Examiner has indicated that page 2 of the information disclosure statement filed October 9, 2003 was not considered because it incorrectly identified the application serial number of the Application. Applicant thanks the Examiner for her suggestion of submitting a new PTO Form 1449 that

references the Application's correct application serial number, which Applicant filed as part of a Supplemental Information Disclosure Statement on April 7, 2004. Applicant respectfully requests that the Examiner enter the Supplemental IDS into the record and send to Applicant an initialed copy of PTO Form 1449 indicating consideration of all the references submitted with the Supplemental IDS.

II. Amendments to the Claims.

Claims 1, 2, 7, 9, 14 and 42-45 have been amended. New claims 50-61 have been added. Support for broadening "methylene-bis-acrylamide" to "cross-linking agent" is found in the specification, considered as a whole, at least at page 12, lines 9-19. Support for broadening the claims from saline solution to aqueous solution is also found in the entire specification considered as a whole, at least at pg. 6, lines 25-31. Additional support for the amendments is likewise found at least at page 8, lines 1-3 and throughout the specification as originally filed. No new matter is presented.

III. Rejections under 35 U.S.C. 102(b).

The Examiner has rejected claims 1-7, 18, 20, 26, 28, 41-46 and 48 under 35 U.S.C. § 102(b) as assertedly anticipated by RU 2034465 to Pavlyk ("Pavlyk"). The Examiner has also rejected claims 1, 3, 5, 6, 18, 20, 26, 41, 46, and 47 under 35 U.S.C. § 102(b) as assertedly anticipated by WO 96/04943. Applicant respectfully traverses these rejections.

It is well established that to anticipate a claimed invention under 35 U.S.C. § 102, a reference must disclose each and every element of the claimed invention either expressly or inherently. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). Furthermore, it is also well established that the reference must be enabling. *In re Epstein*, 31 USPQ2d 1817 (Fed. Cir. 1994).

In the instant case, for each of the two cited references that assertedly anticipate the claimed invention, the Examiner acknowledges that the amount of monomer units in the hydrogel is not disclosed. *See* Office Action at page 3. Thus, by the Examiner's own acknowledgement, the references do not contain each and every limitation of the claimed invention and therefore did not anticipate Applicant's

claimed invention as previously presented. Neither do the references anticipate the Applicant's claimed invention as currently amended.

IV. Rejection under 35 U.S.C. 103(a) to Vogel.

Claims 1-7, 9-15, 18-20, 23, 24, 26, 28-36 and 41-49 stand rejected as obvious over Vogel. Applicant respectfully inquires why the Examiner did not comment on the arguments presented in Applicant's submission that accompanied the RCE. For example, the Examiner has not addressed Applicant's amendment in claim 1 from a polymer "comprising..." to a polymer that "consists essentially of...". Applicant respectfully continues to traverse the rejection, as the significant differences in Vogel do not render Applicant's claimed invention obvious.

As stated by the Federal Circuit, "a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant's disclosure. *Id* at 493. *See also* M.P.E.P. § 2142.

Vogel does not teach, disclose or suggest a hydrogel as claimed by Applicant. Vogel teaches numerous microparticles/microbeads which are biocompatible non-toxic copolymers coated with, linked to, or filled with agents to promote cell adhesion (cell adhesion promoters). Particularly, the microparticles are microbeads or microspheres having a positive charge on the surface of the microparticles to treat urinary incontinence, among other afflictions. Col. 5, lines 41-45, 62-64.

Cell adhesion promoters of Vogel include collagen, gelatin, and other cell adhesion agents. Col. 7 line 65 - Col. 8, line 2. The cell adhesion promoters are introduced in the microbeads by chemical

coupling procedures or by diffusion in the gel network of the microparticles, which traps the diffused molecules by precipitation or cross-linking. Col. 8, lines 26-33. As further shown in Examples 1 and 2 of Vogel - Vogel's only examples of the preparation of hydrogel particles which contain acrylamide - gelatin is added to a solution of monomers. After the gelatin is added, N,N,N,N tetramethyl-ethylene-diamine and ammonium persulfate are added. Both of these compounds are identified by Vogel as initiators. Col. 8, lines 45-50. This demonstrates that Vogel teaches hydrogel microparticles which link additional moieties in the hydrogel which are not acrylamide and a cross-linking agent. Thus, it appears that Vogel's polymer includes a block copolymer of cell adhesion promoters, such as gelatin, and acrylamide. Vogel even identifies the adhesion promoters as "monomers" in describing the preparation of microspheres. Col. 8, lines 19-21.

Conversely, the hydrogel in claim 1 of Applicant's invention, and all claims dependent therefrom, requires a hydrogel of 0.5-25% by weight of a polymer which consists essentially of a polymer prepared by polymerizing acrylamide and a cross-linking agent. Vogel does not teach, disclose, or suggest a hydrogel which comprises a polymer that consists essentially of a polymer prepared by polymerizing acrylamide and a cross-linking agent, much less that such a hydrogel would have desirable properties suitable for the treatment of incontinence or vesicouretal reflux.

Applicant submits that Vogel also does not teach a hydrogel in a form suitable for the treatment of incontinence or vesicouretal reflux. Applicant's hydrogel is substantially homogeneous and is by itself in a form suitable for treatment of incontinence, while Vogel's hydrogel is not described in such a form: it must first be placed in a suspension, which suspension is the form described by Vogel for the treatment of incontinence. Contrasting the fluidity of Vogel's microparticle formulation to the substantially homogeneous hydrogel of Applicant's claimed invention is comparable to contrasting a suspension of sand to molten glass. Even if Vogel taught a composition identical to Applicant's claimed invention, which it does not, Applicant's claimed invention is still directed to a patentably distinct composition from

that taught by Vogel because Vogel does not teach, disclose, or suggest Applicant's claimed product: a hydrogel that is in a form suitable for the treatment of incontinence or vesicouretal reflux which is substantially homogeneous.

Applicant respectfully points out that in Vogel, the hydrogel is not directly injected via a syringe, but the microparticles are first placed in a suspension or formulated into solutions. Col. 6, lines 52-64. As shown further in Examples 13 and 14, both of which describe "Preparations for Injectable Suspensions of Cell-microbeads Particles," the microparticles of Vogel are suspended in serum, preferably at a 1:1 ratio, before injection for treatment. Thus, because Vogel does not teach, disclose, or suggest injecting the hydrogel without first suspending the microparticles in solution, Vogel does not teach or suggest all of the limitations of Applicant's claimed invention, which requires that the hydrogel be in a form suitable for treatment of incontinence or vesicouretal reflux.

Finally, the only teaching of urinary incontinence of any kind in Vogel is by injection of the microparticle/serum suspension into the bladder sphincter, which is a muscle. Conversely, in Applicant's claim 18 and independent claim 54, for example, the hydrogel is injected into one of the ureter, urethra, colon or rectum, all of which are excretory conduits and none of which are muscles. Applicant respectfully submits that one of ordinary skill in the art would not be motivated to directly inject a hydrogel into an excretory conduit to treat incontinence based on a reference that teaches injection of a suspension of microparticles and serum into a bladder muscle.

For at least these reasons, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

IV. Double Patenting Rejection.

Applicant respectfully requests that the double-patenting rejections be held in abeyance until such time as the prior art rejections under 35 U.S.C. § § 102(b) and 103(a) have been withdrawn.

CONCLUSION

For at least the reasons stated above, claims 1-7, 9-20, 23-24, 26, and 28-61 are directed to patentable subject matter. Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. § § 102(b) and 103(a) be withdrawn, following which only the Examiner's double patenting rejection, which is currently in abeyance, will remain.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

This Amendment/Response has been filed within four months of the mailing date of the Office Action. It is believed that the only fee due is a $110.00 fee for a one month extension of time, a check for which is enclosed, and an extra claim fee of $72.00. The Commissioner is authorized to charge the extra claim fee of $72.00 and any additional fees that may be determined to be due to the undersigned's Deposit Account No. 50-0206.

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Respectfully submitted,

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